UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,534	10/14/1999	ELKE BUCHA	209282.0006	7560

570 7590 11/18/2003

AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/18/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/417,534	BUCHA ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-38,42-47 and 50-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-38, 42-47, and 50-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/03 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 6/24/03 is acknowledged and has been entered. Claims 35, 36, and 46 have been amended. Claims 39-41, 48, and 49 have been cancelled. Claims 52-55 have been added. Accordingly, claims 35-38, 42-47, and 50-55 are pending.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

3. The rejections of claims 39-41, 48, and 49 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 35-38, 42-47, are 50-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35, part a) is confusing in reciting, "the structural element (A) of the monomer of the plastics material of the surface". Does Applicant intend, "structural element (A) of the monomer of the surface on the plastic material."

Claim 35, part a) remains vague and indefinite in reciting, "from monomers containing at least one structural element (A) derived from a carboxylic acid" because it fails to specifically define what the "monomers containing at least one structural element (A)" is intended to encompass. Specifically, claim 1, part a) does not recite the specific composition or structure of the "monomers containing structural element (A)" except for the fact the structural element (A) is derived from carboxylic acid; thus, it is unclear how one would be reasonably apprised of the metes and bounds of the claimed invention.

Claim 35, part b) is indefinite in reciting, "capable of" because it fails to recite a positive limitation in the claim.

Claim 35, part c) is vague and indefinite in reciting, "stable interaction" because the term "stable" is a subjective term that lacks a comparative basis for defining its metes and bounds. Further, it is unclear what is encompassed in reciting, "interaction", i.e. binding or unbinding.

Claim 47 remains indefinite in failing to further limit the subject matter of a previous claim. Specifically, claim 47 fails to point out what is included or excluded by the claimed "composition" in comparison to the claimed "interactive system" as recited in claim 35 from which it depends.

Claim 55, part a) is confusing in reciting, "the structural element (A) of the monomer of the plastics material of the surface". Does Applicant intend, "structural element (A) of the monomer of the surface on the plastic material."

Claim 55, part a) is vague and indefinite in reciting, "from monomers containing at least one structural element (A) derived from a carboxylic acid" because it fails to specifically define what the "monomers containing at least one structural element (A)" is intended to encompass. Specifically, claim 1, part a) does not recite the specific composition or structure of the "monomers containing structural element (A)" except for the fact the structural element (A) is derived from carboxylic acid; thus, it is unclear how one would be reasonably apprised of the metes and bounds of the claimed invention.

Claim 55, part b) is indefinite in reciting, "capable of" because it fails to recite a positive limitation in the claim.

Claim 55, part c) is vague and indefinite in reciting, "stable interaction" because the term "stable" is a subjective term that lacks a comparative basis for defining its metes and bounds. Further, it is unclear what is encompassed in reciting, "interaction", i.e. binding or unbinding.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 35, 36, 42, 43, 47, 52, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel (US 4,086,199).

Daniel discloses an interactive system which includes latex polymer particles which function as biological carriers for protein substances. The particles have a plastic material (core) which comprises alkyl acrylates and methacrylates and a cross-linker comprising polyethylene glycol dimethacrylate which gives the polymer particles greater resistance to solvents (see columns 1-2). According to Daniel, the latex particles are very stable, chemically and mechanically, at extended periods of time, remain stable at varying pH levels and temperature (copolymerization temp ranges from 5 to 90 C). The biologically active substances such as proteins are coupled or adsorbed into the carrier particles (see column 4).

6. Claims 35, 36, 42, 44, 47, 50, 51, 52, and 55 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by DeCrosta et al. (US 4,575,539).

Decrosta et al. disclose a drug delivery system in the form of hydrogel beads including interpenetrating polymer network which have superior drug loading and release capacity (see Abstract). Specifically, DeCrosta et al. disclose a first polymer substrate comprising acrylic swelling agent, methyl methacrylate or acrylic acid, and a

crosslinking agent, (poly)ethylene glycol dimethacrylate (see column 3, lines 21-36 and column 5, lines 10-17). The hydrogel beads are allowed to react at a temperature of from about 70C - 120C. The hydrogel beads are loaded with pharmaceutically active compositions wherein the loading is accomplished by coupling the pharmaceutically active compositions with the linker by swelling the hydrogel (see column 8, lines 34-64). The pharmacologically active drugs include those enumerated in column 6, lines 32-62. The drug delivery system allows oral delivery of pharmacologically active substances such as antibiotics for treatment of bacterial and parasitic infections as well as metabolic diseases (see column 4, lines 24-42).

Claims 35, 36, 42, 44, 47, 50, 51, 52, and 55 read on the disclosure as set forth by DeCrosta which provides all the elements as currently recited in the claimed invention. Accordingly, it is maintained that the features recited in the claimed invention, i.e. a stable interaction exists between the surface and the linker which comprises hydrogen bonds and which cannot be reversed by pH in the range of from 2-13 or temperatures up to 60 C, are inherently taught by DeCrosta.

7. Claims 35-38, 42-47, and 50-55 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by Hubbell et al. (US 5,410,016).

Hubbell et al. disclose an interactive system comprising photopolymerizable, biodegradable hydrogels used as tissue contacting materials or controlled release carriers (see columns 1 and 2, especially column 3, line 53 to column 4, line 27 and column 10, line 50 to column 11, line 17). Specifically, the interactive system has a

polymerizable region which comprises dimethacrylates and oligomethacrylates. The polymerizable region may contain a reactive derivative such as isocyanate or isothiocyanate. The polymerizable, macromer includes a core, an extension on each end, and an end cap wherein the core includes hydrophilic polyethylene glycol (see column 9, lines 7-18 and column 8, lines 5-48). The physiologically and pharmacologically active drugs coupled to the linker for controlled delivery include proteins, hormones, enzymes, antibiotics, and carbohydrates which include hyaluronic acid, heparin, and heparan sulfate (see column 10, lines 20-48). See especially Example 16.

Claims 35-38, 42-47, and 50-55 read on the disclosure as set forth by Hubbell et al. which provides all the elements as currently recited in the claimed invention. Accordingly, it is maintained that the features recited in the claimed invention, i.e. a stable interaction exists between the surface and the linker which comprises hydrogen bonds and which cannot be reversed by pH in the range of from 2-13 or temperatures up to 60 C, are inherently taught by Hubbell et al.

Response to Arguments

8. Applicant's arguments filed 6/24/03 have been fully considered but they are not persuasive.

A) Applicant argues that claim 35, part a) now recites that the plastic material is a "polymethacrylate polymer, a polyvinyl ester polymer, or copolymers thereof"; accordingly, claim 35 definitely and properly recites the specific structures of the

"monomers that contain at least one structural element (A)" when read in light of the specification description, e.g. pages 3-5.

In response, while claim 35 has defined the composition of the plastic material as being selected from "polymethacrylate polymer, a polyvinyl ester polymer, or copolymers thereof", it still fails to define what the "one surface of the plastic material from monomers containing at least one structural element (A) that is derived from carboxylic acid" is intended to encompass. Specifically, the specification at page 3 provides that the *plastic material* comprises the structural element as set forth after line 4, which is the same *structural element (A)* provided in page 4, which is said to be part of a polymer of the same *general formula (I)* in page 5. Thus, it remains unclear what the structural element (A) is still intended to encompass.

B) Applicant argues that Daniel does not teach the claimed invention because Daniel does not teach the three components recited in claim 35, i.e. part a) plastic material, part b) linker, and part c) substance. Applicant contends that Daniel does not teach that the components that are parts a and b are related to one another in a specific manner, that is, their "interaction" comprises hydrogen bonds of a very specific nature – they cannot be reversed by pH in the range of from 2-13 or temperatures up to 60 C. Applicant specifically argues that Daniel instead only teaches polymer particle latexes wherein the particles comprise a core such as alkyl acrylates and methacrylates, that the monomer may be hydrogen bonded and also that it is provided with a cross-linker such as polyethylene glycol. According to Applicant, the core component is associated

with the periphery of the component by polymerization which requires the formation of covalent bonds which is different from the claimed invention which requires that the interaction between elements A) and B) comprises hydrogen bonds.

Contrary to Applicant's argument, Daniel, indeed, discloses the interactive system in the form of "latex polymer particles" which function as biological carriers for protein substances. These particles have 1) a plastic material (core) which comprises alkyl acrylates and methacrylates, i.e. a plastic materials that are made from monomers and contains at least one structural element (A) derived from carboxylic acid, 2) a cross-linker comprising polyethylene glycol, i.e. a linker with at least one structural element (B) that is capable of establishing a hydrogen, which gives the polymer particles greater resistance to solvents, and 3) biologically active substances such as proteins coupled to the linker and adsorbed into the carrier particles. According to Daniel, the latex particles are very stable, chemically and mechanically, at extended periods of time, remain stable at varying pH levels and temperature, i.e. 5C to 90C.

In response to Applicant's contention that Daniel fails to teach the required interaction between elements A) and B) as comprising hydrogen bonds, it is noted that the features upon which applicant relies (i.e., stable interaction comprising hydrogen bonds) is not recited in the rejected claims. Claims 35 and 55 only recite that "the structural element B) is capable of establishing a hydrogen bond" and that "the structural element B) comprises of hydrogen bonds". As such, claims 35, 36, 42, 43, 47, 52, and 55 do not exclude the teaching of polymerization or covalent bond formation between elements by Daniel.

C) Applicant argues that DeCrosta does not teach the claimed invention because Decrosta does not teach the three components recited in claim 35, i.e. part a) plastic material, part b) linker, and part c) substance. Applicant contends that DeCrosta does not teach that the components that are parts a and b are related to one another in a specific manner, that is, their "interaction" comprises hydrogen bonds of a very specific nature – they cannot be reversed by pH in the range of from 2-13 or temperatures up to 60 C. Applicant specifically argues that DeCrosta instead only teaches a drug delivery system as an interpenetrating polymer network wherein the first polymer (core component) is associated with the second polymer (periphery of the component) by polymerization which requires the formation of covalent bonds which is different from the claimed invention which requires that the interaction between elements A) and B) comprises hydrogen bonds.

Contrary to Applicant's argument, DeCrosta, indeed, disclose hydrogel beads, i.e. a drug delivery system, which include a first polymer substrate comprising acrylic swelling agent, methyl methacrylate or acrylic acid, i.e. a plastic material that is made from monomers and contains at least one structural element (A) derived from carboxylic acid, and a crosslinking agent, (poly)ethylene glycol dimethacrylate, i.e. a linker with at least one structural element (B) that is capable of establishing a hydrogen. The hydrogel beads are loaded with pharmaceutically active substances by coupling the pharmaceutically active substance with the linker by swelling the hydrogel. The drug delivery system allows oral delivery of pharmacologically active substances such as

antibiotics for treatment of bacterial and parasitic infections as well as metabolic diseases.

In response to Applicant's contention that DeCrosta fails to teach the required interaction between elements A) and B) as comprising hydrogen bonds, it is noted that the features upon which applicant relies (i.e., stable interaction comprising hydrogen bonds) is not recited in the rejected claims. Claims 35 and 55 only recite that "the structural element B) is capable of establishing a hydrogen bond" and that "the structural element B) comprises of hydrogen bonds". As such, claims 35, 36, 42, 44, 47, 50, 51, 52, and 55 do not exclude the teaching of polymerization or covalent bond formation between elements by DeCrosta.

D) Applicant argues that Hubbell does not teach the claimed invention because Hubbell only teaches the component parts of the hydrogel as being associated with one another by polymerization which requires the formation of covalent bonds which is different from the claimed invention which requires that the interaction between elements A) and B) comprises hydrogen bonds.

Hubbell discloses photopolymerizable, biodegradable hydrogels , i.e. an interactive system, which comprises dimethacrylates and oligomethacrylates. The polymerizable, macromer includes a core, an extension on each end, and an end cap wherein the core includes hydrophilic polyethylene glycol, i.e. linker. Hubbell et al. disclose coupling the physiologically and pharmacologically active drugs to the linker for controlled delivery of proteins, hormones, enzymes, antibiotics, and carbohydrates.

Further, Hubbell et al. show in Example 16 wherein anticoagulants such as hyaluronic acid, i.e. heparin or heparan sulfate, are coupled to the polyethylene glycol linker.

In response to Applicant's contention that Hubbell fails to teach the required interaction between elements A) and B) as comprising hydrogen bonds, it is noted that the features upon which applicant relies (i.e., stable interaction comprising hydrogen bonds) is not recited in the rejected claims. Claims 35 and 55 only recite that "the structural element B) is capable of establishing a hydrogen bond" and that "the structural element B) comprises of hydrogen bonds". As such, claims 35-38, 42-47, 50, 51, and 55 do not exclude the teaching of polymerization or covalent bond formation between elements by Hubbell.

9. For reasons aforementioned, no claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
November 13, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641